

Applicant : Douglas A. Devens, Jr.
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Attorney's Docket No.: 10527-396001 / 02-027

REMARKS

Applicants have withdrawn claims 23, 25, and 26, and canceled claim 22, without prejudice. Claims 1-21 are presented for examination.

Claim 1, the only independent claim, recites a medical device comprising at least four coextruded layers comprising a first material and a second material having a different stiffness than a stiffness of the first material, wherein at least one of the layers varies in thickness axially along the device.

Under 35 U.S.C. § 103(a), claim 1 is rejected as being unpatentable over U.S. Patent No. 6,030,369 (Engelson) in view of U.S. Patent No. 5,730,733 (Mortier); and claims 2-21, which depend from claim 1, are rejected as being unpatentable over Engelson in view of Mortier and further in view of U.S. Patent Nos. 5,562,127 (Fanselow) and 6,776,945 (Chin). In particular, the Examiner has relied on Engelson for disclosing a catheter having the claimed two coextruded layers, but the Examiner has acknowledged that Engelson does not disclose catheters having four or more coextruded layers. To make up for Engelson's deficiencies, the Examiner has relied on the secondary and tertiary references for disclosing devices with four or more layers, although none of these references discloses or suggests the claimed at least four coextruded layers, wherein at least one of the layers varies in thickness axially along a device. According to the Examiner, because the secondary and tertiary references disclose catheters having four or more layers, increasing or duplicating the number of coextruded layers in Engelson would have been considered obvious. This reasoning, however, is not supported by the references or the understanding of one skilled in the art.

It is clear from Engelson itself that catheters having four or more layers were known, so the secondary and tertiary references do not really add anything to Engelson. For example, in the Background section, Engelson refers to U.S. Patent No. 4,994,047 (Walker) that describes a coextruded cannula having five layers (*see, e.g.*, Walker, Fig. 5). But in spite of knowing this, Engelson's description of its invention is limited to catheters having two layers because having only two layers is consistent with Engelson's goal to make a small diameter catheter for neurological and peripheral vascular applications (*see, e.g.*, Engelson, col. 3, lines 36-39 and 47-51). There is no teaching or suggestion whatsoever in Engelson's description to make a catheter

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having more than two layers even though Engelson clearly knew about catheters having more than two layers. As a result, the Examiner's assertion that increasing or duplicating the number of coextruded layers in Engelson would have been considered obvious is not only unsupported by Engelson, but it is contrary to Engelson's goal because merely increasing the number of layers, without more, would undesirably increase the diameter of Engelson's catheter. Indeed, given that Engelson's catheter apparently can provide both trackability and pushability in a small diameter profile, one skilled in the art reading Engelson would have been motivated to keep the number of layers low, not increase the number of layers, as suggested by the Examiner.

Increasing the number of co-extruded layers would also be contrary to the understanding of one skilled in the art. For example, increasing the number of layers of a device would increase the dimensional profile, complexity (e.g., compatibility of the layers), and cost of the device. One skilled in the art would have wanted to minimize or at least to reduce the dimensional profile, complexity, and/or cost of a device. So absent a recognition that increasing the number of layers is somehow desirable, one skilled in the art would not have been motivated to increase the number of layers.

Here, the Examiner has not pointed to any suggestion in the references or in the knowledge of one skilled in the art to increase the number of layers. Rather, the Examiner has only conclusorily asserted that increasing or duplicating the number of coextruded layers in Engelson would have been considered obvious. Accordingly, Applicants request that the Examiner provide a supported motivation to modify Engelson's catheter either from the cited references (which is to be consistent with the teachings of Engelson) or from the knowledge of one skilled in the art.

Applicants note that the desirability of having a multitude of co-extruded layers has only been expressed by Applicants' specification. In particular, Applicants stated:

Without wishing to be bound by theory, it is believed that the multitude of layers provides tube 10 with a relatively gradual transition between different portions or layers of materials, and differing physical properties, e.g., stiffness. It is believed that an abrupt transition can cause a tube to be more susceptible to unpredictable kinking or buckling, which can occur during use and is typically undesirable. By using a multitude of layers, the materials are distributed evenly to approximate homogenous blending or mixing of the

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materials, e.g., as in a solid solution, so that there is a reduced possibility of a localized concentration of a material that can disproportionately contribute to tube 10.

(see page 5, line 27 – page 6, line 3). None of the cited references discloses or suggests this desirability.

In light of the above remarks, Applicants request that the rejections be reconsidered and withdrawn.

Under 35 U.S.C. § 103(a), claim 22 is rejected as being unpatentable over U.S. Patent No. 4,790,831 (Skribishi) in view of Engelson and Mortier. Claim 22 has been canceled, so this rejection should be withdrawn.

For at least the reasons discussed above, Applicants believe the claims are in condition for allowance, which action is requested.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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